the claims. The difficulty with the Examiner's interpretation of claim 17 is that it has run two parts of the claim together. The claim is directed to a method that comprises combining an active ingredient that comprises a steroidal aromatase inhibitor and contains no antigestagens with a substance for promoting skin penetration. The promoting of skin penetration provided by the claimed substance is "so as to avoid systemic action of the active ingredient." Thus, it is clear from the claims that it is the active ingredient that contains no antigestagens and that the substance for promoting skin penetration is a different substance from the active ingredient, which both contains a steroidal aromatase inhibitor and contains no antigestagens. The claim language is not, as a result, properly read as the Examiner seems to read it and is clear to persons skilled in the art.

The Examiner also says that the phrase "containing a substance for promoting skin penetration... avoids systemic action" renders the claims indefinite "because it is unclear how, if [a] penetration enhancer which promotes systemic absorption of the steroidal aromatase inhibitors is comprised in the composition, systemic activity of the steroidal aromatase inhibitor would be totally absent in the body." Applicants respectfully submit that there are two separate problems with the Examiner's interpretation. First, the Examiner has misread the language of claim 17, which says that the combination of the substance with the active ingredient produces the function of promoting skin penetration while avoiding systemic action of the active ingredient. Thus, the substance encompassed by the claims does not, contrary to the Examiner's apparent interpretation, promote systemic absorption of the steroidal aromatase inhibitors comprised in the composition. The claim language as it stands is clear to persons skilled in this art to convey this meaning.

The second difficulty with the Examiner's logic is that it confuses enablement with indefiniteness. It is not the function of the claims to explain how the invention is carried out but rather to simply define the meets and bounds of the invention so that persons skilled in the art will know whether their activities are within or without the scope of the claims. Thus, persons skilled in the art reading the claims in this application would understand that they are not

practicing the method of the claimed invention if they use a substance for promoting skin penetration in a way that allows systemic action of the active ingredient combined with the substance for promoting skin penetration.

For the foregoing reasons, applicants respectfully submit that the claims as presented in this application are clear in their scope to persons skilled in the art and that the rejection of claims 17-24 under 35 USC 112, second paragraph, should be withdrawn.

Claims 17-24 stand rejected under 35 USC 103(a) on Brodie and Messenger in view of Hanson. The Examiner cites Messenger as teaching a process of making a topical formulation of a steroidal aromatase inhibitor that contains no antigestagens, citing page 10, lines 10-15, and Example 1, page 28, of Messenger. Brodie is cited as teaching a pharmaceutical formulation of a steroidal aromatase inhibitor that is administered to a host for sustained release, referring to page 369, column 2, 2nd paragraph, of Brodie. The Examiner admits that the references do not teach that the formulation contains a penetration promoting agent and do not teach the formulation of the steroidal aromatase inhibitor as a topical formulation. Hanson is cited for teaching DMSO as being useful as a penetration promoting agent in local administration of drugs, referring to page 1218, first column, "Uses" section. The Examiner reasons that it would have been obvious for a person of ordinary skill in the art at the time the invention was made to formulate a steroidal aromatase inhibitor into a topical formulation and that likewise it would have been obvious at the time the invention was made to use DMSO as a penetration promoting agent in the topical formulation of the steroidal aromatase inhibitor. The Examiner further indicates the belief that Messenger would have motivated a person of ordinary skill in the art to formulate 4-O-acetylandrost-4-ene-3, 17-dione into a topical formulation with no antigestagen and a penetration promoting agent "because Messenger suggests that the topical formulation therein containing no antigestagen may employ any known aromatase inhibitor including 4-O-acetylandrost-4-ene-3, 17-dione.

Based on this logic, the Examiner challenged applicants to demonstrate unexpected results over the prior art and argued on page 5 of the Action that the method of making the

mastocarcinoma treatment composition claimed "is clearly obvious in view of the cited prior art which suggests the usefulness of effective amounts of aromatase inhibitors herein in a composition with a penetration enhancing agent, [in the] absence of antigestagens." This rejection and its supporting reasoning are respectfully traversed.

In all of the discussion of the prior art, the Examiner has overlooked a significant aspect of the claimed invention, the requirement of all of the claims that the combining of the substance for promoting skin penetration with the active ingredient in accordance with the claimed method be carried out "so as to avoid systemic action of the active ingredient." There is no evidence whatever in this record that it would have been obvious to persons of ordinary skill in the art to make or practice this aspect of the claimed invention. The Examiner pays no attention whatever to this significant limitation of all the claims. Without evidence of a motivation to combine a substance for promoting skin penetration with the claimed active ingredient so as to produce this explicitly claimed result of the claimed method, there is no *prima facie* case of obviousness for applicants to rebut, contrary to the Examiner's statement at the top of page 5 of the Action.

To the argument at the bottom of page 5 of the Action, applicants respectfully respond that the method as claimed is, indeed, a method of making a medicament, carried out so that the medicament produced has the property claimed of avoiding systemic action of the active ingredient. This is a proper limitation of a method of manufacture claim and is not a mere statement of intended use that does not lend patentable weight to claims drawn to a method of making a product. As applicants have stressed above, methods of making products that do not produce a product with the claimed characteristics are not within the scope of the claims of this application.

Applicants believe that a further comment on the scope of the claims is necessary in response to the Examiner's comments on the bottom of page 5 of the Action. The Examiner is not legally correct in dismissing the preamble limitation that the medicament whose method of making is claimed is "for the prophylaxis or treatment of mastocarcinoma." The reason this is is that the choice of a substance for promoting skin penetration and the amount of the substance

combined with the effective amount of the active ingredient depends upon where and how the medicament is to be used. As the specification of this application explains, the choice of skin penetration promoting agent is made keeping in mind the fatty nature of the tissue to be treated and is not done indiscriminately. The claimed method is not an open-ended method of combining two ingredients; rather, it is a method for making a medicament that, because of its particular intended use, has certain characteristics that the method of making the medicament must produce in the end product. For this reason, persons of ordinary skill in the art would not have been motivated by the cited prior art to arrive at the claimed invention, because teachings in unrelated fields such as treatment of baldness (Messenger), for example, would not have motivated anyone trying to make a medicament for the prophylaxis or treatment of mastocarcinoma to do anything in particular regarding the ingredients of that medication.

For the foregoing reasons, early action allowing claims 17-24 in this application is solicited.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 246472001600.

Respectfully submitted,

Dated: September 27, 2002 By: _____

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